

October 18, 2005

European Patent Office
D-80298 Munchen
Germany.

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Dear Sirs,

Re. : INDIA - PCT Application No. PCT/IN04/00142

Dated - May 20, 2004

Claiming Priority on IN/PCT/04/000064 dated 19/3/2004 and
563/MUM/2004 dated 17/5/2004

For - "AN IMPROVED PROCESS FOR PRODUCING CHLORI-NATED SUCROSE"

Applicant: Pharmed Medicare Pvt. Ltd.

International Publication No: WO 2005/090374 A1

This is with reference to above mentioned PCT application. The PCT application has been published as WO 2005/090374 A1. Now, with this letter, we are submitting Demand for International Preliminary Examination with following documents:

1. Formal Form of PCT Demand for International Preliminary Examination.
2. Demand Draft in the name of European Patent Office for EURO 1659/- towards International Preliminary Examination Fees and Handling Fees.
3. Addition of matter had been done at some places in the description in the "as filed application with amended claims under Article 19(1)" application in view of the requirements to clarify the comments of International Searching Authority on Claim nos. 24 and 25. The addition of matter has resulted in change in format of the "as filed as filed application with amended claims under Article 19(1)" application. The changes at several places has extensively changed the format and layout of the entire document. Hence, the entire document "PCT-IN04-142 replacement application amended under Article 34" which contains changes incorporated in "as filed as filed application with amended claims under Article 19(1)" application has been enclosed herewith. This document may be considered as replacing the "as filed" document in its entirely. The entire replacement document is exactly same as the "as filed" application except the following details of the locations which are additions in the context of "as filed" application:

- a. Line no. 10 and 11 on page no. 7 of "PCT-IN04-142 replacement application amended under Article 34"
- b. From line no. 14 of page no. 23 up to and including line no. 17 of page no. 26 of the "PCT-IN04-142 replacement application amended under Article 34"
- c. At line 13 and 14 of the words ", majority of particles being" on page no. 34 of "PCT-IN04-142 replacement application amended under Article 34"
- d. Deletion of "31." at line no. 3 and addition of "of" at line no. 6 between words "sucrose" and "one" on page no. 35 of the "PCT-IN04-142 replacement application amended under Article 34".

4. Two figures, **Figure no. 7** and **Figure no. 8** have been added and these sheets has been attached along with the replacement document "PCT-IN04-142 replacement application amended under Article 34" mentioned in item number 3 above.

5. A "**Statement under Article 34**" that have been mentioned in item no. 2 and 3 above has been enclosed herewith.

6. We are also enclosing herewith for your ready reference following documents filed with :

- a. Copy of the **International Search Report** received from the International Searching Authority.
- b. Copy of **Statement under Article 19(1) (Rule 46.4)** filed with the report filed with International Bureau, WIPO, and
- c. Copy of **amended claims** filed with report filed with International Bureau, WIPO.

We trust that the amended specification attached with the demand satisfies your examination, needing no further interaction. However, if there is any necessity of explanation from our side on any points, we shall be prepared to diligently send you our responses immediately on your written opinions and as many time as is possible within the time available to ensure that your queries are satisfied.

Kindly acknowledge receipt of above documents and oblige.

Yours faithfully,
FOR KRISHNA & SAURASTRI

(UMA BASKARAN)

Encl. : As above.

10/593158

Statement under Article 34

Pursuant to amendments in claims done under Article 19 (1), it was imperative to make corresponding amendments in description under Article 34. The amendments are fully within the scope of the contents of and disclosures made in the "as filed" PCT application. Amendments made under Article 34 have been directly incorporated into the "as filed application with amended claims under Article 19(1)" PCT application and the amended application is presented with this statement as "**PCT-IN04-142 replacement application amended under Article 34**", which is proposed to serve as a replacement document to the "as filed" application.

The amended portions of the document "**PCT-IN04-142 replacement application amended under Article 34**", are either additions or deletions done at appropriate place and the places of these additions and deletions are clearly identified below. Rest of the portion of the replacement document is exact copy of "as filed" application. The details of the amended portion and reasons for the amendments are as follows:

1. **Addition of matter at Line no. 10 and 11 on page no. 7 of "PCT-IN04-142 replacement application amended under Article 34"**: This addition is necessitated by addition of two figures numbered 7 and 8. These figures themselves are necessary to be added due to the addition of matter detailed in item no. 2 below and why this addition is within the scope of disclosures made in "as filed" application has been explained in item no. 2 below.
2. **Addition of matter from line no. 14 of page no. 23 up to and including line no. 17 of page no. 26 of the "PCT-IN04-142 replacement application amended under Article 34"**: This is description of the properties of the products produced by the process of claim nos. 1 to 23. We intended to cover this description in claim nos. 24 and 25 of the "as

“as filed” application. The claim nos. 24 and 25 in “as filed” application are as follows:

“24. A product or composition or its intermediate or its derivative obtained after drying either in solid form or its any derivative in liquid form or a composition with or without other components when the resulting product is any product prepared by any process of claim 1 to 23 directly essentially as described or adapted suitably by making suitable modifications but retaining drying of liquid reaction mixtures or liquids obtained in process as a part of the process used.

25. A product or composition to which the product or composition or its intermediate or its derivative of claim no. 24 has been added as a component.”

The meaning of above two claims we had in mind was to claim all the novel properties of the product with respect to properties such as particle shape, size, solubility, stability etc. which shall arise due to use of process of claim 1 to claim 23 and compositions prepared from use of such products as an ingredient.

However, the International Searching Authority (ISR) construed the meaning that we are claiming a New Chemical Entity as result of process of claim 1 to 23 and hence the ISR has remarked that the process of claim 1 to 23 shall lead to production of a known chemical entity “sucralose”, and since just a new process can not claim the product as novel product if it has produced a known chemical entity, the claim nos. 24 and 25 lack novelty.

This was clearly a misunderstanding of our intention, which we needed to point out and take remedial measures as response to ISR. Opinion of ISR was based on a premise which was not in our mind and was not claimed, it was something different.

After pointing out in the ISR that what has been construed by ISR is not what we had intended, we felt that it may be a good idea to resort to redrafting the claim nos. 24 and 25 in more explicit manner, drawing specific and express attention to the fact of novel particle forms the process of claim no. 1 to 23 creates. **Accordingly, in the informal response to ISR, the claim nos. 24 and 25 were dropped and claim nos. 24 to 31 were added including the details we intended to cover in the claims nos. 24 and 25 of the “as filed application.**

The mention of novel forms which resembled amorphous form was already made in the description of “as filed” application. However, now to support the details given in the claim nos. 24 to 31 of the revised claims, it is necessary to give the details in the description based on which the claims are made.

Hence, the description which was not given in the “as filed” application, being a routinely checked and kept data of the products prepared in experimentation, and which were considered as avoidable detail once ALL the properties of the products prepared by process of claims 1 to 23 were claimed in claim nos. 24 and 25 of “as filed” application, are now seen to be necessary to be given simultaneous with dropping the claim nos. 24 and 25 of “as filed” application and replacing them with the revised claim nos. 24 to 31 which claim particle size etc., details of which were not included in the description earlier.

Hence, analytical data on some of the batches prepared by process of claim nos. 1 to 23 is given as an addition in this item.

We humbly invite the kind attention of the Authorised Officers of the International Preliminary Examination Authority that **this additional information is fully within the scope of the spirit of the subject matter as disclosed in the “as filed” application**, and does not add any new

element of disclosure and does not increase the width of the disclosure, because the properties pertain to the products as produced by the process of claim nos. 1 to 23 which are well within the scope of the invention disclosed in the “as filed” application. They are only petty routine voluminous details of analysis which were considered as unnecessarily inflating the body of the application having no relevance if a comprehensive claim is made as done in claim nos. 24 and 25 of the “as filed” application. Hence, we request that the addition of the information as proposed in this item be kindly accepted and allowed.

3. At line 13 and 14, insertion of the words “, majority of particles being” in claim no. 29 (i) on page no. 34 of “PCT-IN04-142 replacement application amended under Article 34”: These words only seek to represent the data provided in the relevant tables in more descriptive fashion. This is within the scope of product produced by process of claim nos. 1 to 23, which have been already disclosed in the “as filed” application. Hence, it is humbly requested that the amendment be kindly allowed.
4. Deletion of “31.” ,Which was present at the beginning of claim no. 31, at line no. 3 and addition of “of” in the same claim between words “sucrose” and “one” at line no. 6 in the same claim on page no. 35 of the “PCT-IN04-142 replacement application amended under Article 34”: Deletion of the expression “31,” pertains to making a simple typographic error correction. Plain reading of the claim no. 31 in the amended claims will make it clear that the expression “31,” at the beginning of the sentence of claim no. 31 is totally out of place and could not have been intended to be written at that place. It has no meaning of itself, nor does its removal lead to change in meaning of the claim. It has no relevance to the scope of invention as disclosed in the “as filed” document also. Hence, we humbly request that proposed deletion be allowed.

5. Two figures, Figure no. 7 and Figure no. 8 have been added and these sheets have been inserted in the “PCT-IN04-142 replacement application amended under Article 34”: These figures pertain to the physical properties of the products prepared by claim nos. 1 to 23 of the “as filed” application and are related to the description given as additional with the revised document which is being filed with this Demand of IPER. Since they pertain to the matters covered by process of claim nos. 1 to 23, which are already disclosed in the “as filed” application, there is no new element of disclosure and hence may please be allowed.

We trust that the amended specification attached with the demand satisfies your examination, needing no further interaction. However, if there is any necessity of explanation from our side on any points, we shall be prepared to diligently send you our responses immediately on your written opinion and as many time as is possible within the time available to ensure that your queries are satisfied.

Signature :

Name : UMA BASKARAN

(Agent of Pharmed Medicare Pvt. Ltd.)